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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09X68,779	08/20/2001	Katsuke Teshigawara	3813-0101P	6309

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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0632

DATE MAILED 02/24/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,779

Applicant(s)

Teshigawara

Examiner

Anne Marie Wehbé

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/25/02, 12/13/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 11, 13, 15, 17, 19, 21, and 22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 13, 15, 17, 19, 21, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) (Paper No.): |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) |
| 3) Information Disclosure Statement(s) (PTO-1449) (Paper No.): | 6) Other: |

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DETAILED ACTION

Applicant's amendments and response received on 10/25/02 and 12/13/02 have been entered. Claims 10, 12, 14, 16, 18, and 20 have been canceled. New claims 21-22 have been added. Claim 9, 11, 13, 15, 17, 19, and 21-22 are currently under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action, can be found in the previous office actions.

Claim Rejections - 35 USC § 112

The rejection of claims 15-20 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's cancellation of claims 16, 18, and 20, and in view of applicant's amendments to claims 15, 17, and 19.

The rejection of claims 14 and 20 under 35 U.S.C. 112, second paragraph for indefiniteness is withdrawn in view of the cancellation of these claims.

Applicant's amendments to claims have necessitated the following new grounds of rejection.

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Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite, "the method according to claim 9, wherein said cancer cells are stimulated by class-I negative cancer cells.....". Claim 9 does not recite any limitation relating to the stimulation of cancer cells. Claim 9 recites a method of culturing anti-cancer lymphocytes in vitro by incubating lymphocytes with cancer cells. Claim 9 does not provide any antecedent basis for the word "stimulated". Further, the method of claim 9 would result in the stimulation of the lymphocytes not the cancer cells.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite, "the composition according to claim 15, wherein said lymphocytes are stimulated by class-I negative cancer cells.....". Claim 15 does not provide any antecedent basis for the word "stimulated". Claim 15 recites the incubation of lymphocytes with cancer cells wherein the lymphocytes are amplified.

Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite, "the method according to any one of claims 15, 17, 19". Claims 15, 17, and 19 are composition claims, not method claims.

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Claim Rejections - 35 USC § 102

The rejection of claims 9-20 under 35 U.S.C. 102(a) as being anticipated by Kim et al. is maintained over pending claims 9, 11, 13, 15, 17, 19, and 21-22. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the methods taught by Kim et al. include the use of IL-2 and that the instant methods do not require the use of IL-2. Applicant's amended claims 9, 11, and 13 recite methods of culturing anti-cancer lymphocytes *in vitro* comprising incubating lymphocytes with cancer cells under conditions to amplify NK cells or MHC-bound antigen specific killer T cells, wherein the lymphocytes are activated by an immunomodulator increasing cancer cell killing activity of the lymphocytes. Applicant's methods thus clearly recite the use of an immunomodulator which increases the cancer cell killing activity of lymphocytes. IL-2 is a well known and well characterized cytokine which not only stimulates but enhances CTL activity. Thus, IL-2 meets the applicant's definition of immunomodulator. The fact that the claims do not specifically recite the use of IL-2 is irrelevant, as the claims recite the use of an immunomodulator, and IL-2 is an immunomodulator. Further, the applicant is reminded that the method claims utilize the open terminology "comprising". Thus, the claimed methods may include steps not specifically recited.

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In regards to the composition claims, claims 15, 17, 19, and 21-22, the applicant is reminded that these claims are product-by-process claims. However, as discussed in detail in the previous office action, in product by process claims, the process used to create the product must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Case law states that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). Thus, for the purpose of analysis under 102, the applicant's composition claims read on a composition of anti-cancer lymphocytes. The applicant has not provided any evidence which

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demonstrates that the anti-cancer lymphocytes taught by Kim et al. are structurally or functionally different from the anti-cancer lymphocytes taught by the specification.

The rejection of claims 9-20 under 35 U.S.C. 102(b) as being anticipated by Liu et al. is maintained over pending claims 9, 11, 13, 15, 17, 19, and 21-22. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the methods taught by Liu et al. include the use of IL-2 and IL-4, and that instant methods do not require the use of these cytokines. Applicant's amended claims 9, 11, and 13 recite methods of culturing anti-cancer lymphocytes *in vitro* comprising incubating lymphocytes with cancer cells under conditions to amplify NK cells or MHC-bound antigen specific killer T cells, wherein the lymphocytes are activated by an immunomodulator increasing cancer cell killing activity of the lymphocytes. Applicant's methods thus clearly recite the use of an immunomodulator which increases the cancer cell killing activity of lymphocytes. IL-2 is a well known and well characterized cytokine which not only stimulates but enhances CTL activity. Thus, IL-2 meets the applicant's definition of immunomodulator. The fact that the claims do not specifically recite the use of IL-2 is irrelevant, as the claims recite the use of an immunomodulator, and IL-2 is an immunomodulator. Further, the applicant is reminded that the method claims utilize the open terminology "comprising". Thus, the claimed methods may include steps not specifically recited.

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In regards to the composition claims, claims 15, 17, 19, and 21-22, the applicant is reminded that these claims are product-by-process claims. However, as discussed in detail in the previous office action, in product by process claims, the process used to create the product must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Case law states that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). Thus, for the purpose of analysis under 102, the applicant's composition claims read on a composition of anti-cancer lymphocytes. The applicant has not provided any evidence which

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demonstrates that the anti-cancer lymphocytes taught by Liu et al. are structurally or functionally different from the anti-cancer lymphocytes taught by the specification.

No claim are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's

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supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbe

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

